Response ID ANON-2GJY-VC1P-P

Submitted to Modernising My Health Record – Sharing pathology and diagnostic imaging reports by default and removing consumer access delays
Submitted on 2023-10-31 12:01:16

Privacy and Your Personal Information

1 Response Collection Consent

I consent to the Department collecting the information requested in Citizen Space about me, including any sensitive information, for the purposes indicated above.:
Yes

About you

1 What is your name?

Name:
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2 What is your email address?

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3 Are you responding as an individual or on behalf of an organisation?

On behalf of an organisation

4 If you are responding on behalf of an organisation, please provide the name of the organisation:

Organisation's name:
Australian Genomics

5 Do you categorise yourself as a:

Professional body / peak organisation

Other Catagory:
Research organisation

6 Do your responses relate to:

Pathology services

Better access – sharing pathology and diagnostic imaging reports to My Health Record by default

1 What systems, processes or standards exist in the community (or need to be put in place) to ensure that providers can comply with this initiative from December 2024?

List systems, processes or standards that exist in the community to ensure provider compliance with this initiative from December. 2024:

As outlined in the consultation paper, there are some tests / in some jurisdictions where sharing by default is not appropriate. Not discussed in the consultation paper is the availability of the results of genetic and genomic test reports. There are several reasons and circumstances whereby Australian Genomics strongly believes that it is not appropriate for genetic or genomics test results to be shared to MyHR, at least until the results are discussed with the patient by a healthcare professional (HCP). Reasons for this include:
1) Genetic/genomic test results often have implications for family members. This can be a sensitive discussion, and patients often need support from their HCP to understand both the results and the implications and communicate this information to family members.
2) Frequently, follow up investigations (such as segregation testing, review of phenotype) are needed to enable more accurate interpretation of the result, and these are arranged during return of results consultations. For this appointment to go ahead is therefore important in terms of clinical management, and so any impacts associated with the patient having had the report available to view independently beforehand should be considered.
3) Genetic/genomic test reports can be complex, and generally require clinical interpretation - a full and correct interpretation of reports by patients by themselves is highly unlikely.
4) Concerns about privacy and discrimination may lead patients to decide they do not want such reports stored on MyHR or they want to control the visibility of them if they are.
Australian Genomics strongly suggests that if genetic/genomic test results are shared to MyHR it is only done after the result has been returned to the patient by an HCP. The only exceptions that could be considered at this time include the case of a low chance reproductive carrier screening result or results of pharmacogenomic tests.

The Australian Government will need to consider the process(es) for individuals to control who can access their pathology and imaging reports. This will need to include whether two mechanisms are appropriate: 1) an option to 'opt out' is included on all diagnostic imaging and pathology consent forms, and 2) via visibility and access controls in My Health Record (MyHR). We support the maintenance of an upfront, paper-based method of opting out, for those who do not access their MyHR regularly. Consumers need to be given an easy opportunity to opt out, and whether logging into their MyHR for every test ordered that they want to opt out of sharing results for constitutes an easy process will need to be considered.

The other consideration relates to who has overarching authority to upload reports. Are diagnostic laboratories given authority over the referring clinical services to upload reports to MyHR?

The Mackenzie's Mission Australian Reproductive Carrier Screening Study delivered low chance genomic test results to participants through an online portal, with evidence of acceptability to participants. Additionally, when we asked research participants in a clinical genomics project offering genomic testing using Australian Genomics' dynamic consent platform CTRL if they would like a copy of their genomic test report stored securely online, 87% participants said yes.

2 What change and adoption strategies are needed to enable sharing to My Health Record by default?

List change and adoption strategies required to enable sharing to My Health Record by default:

Laboratories providing genomic testing currently do not have - but will need to have in place – laboratory information management systems that align with new NPAAC standards for genetic/genomic consent – where patient consent for clinical data sharing, research data sharing, and MyHR opt out are required. Labs are concerned about the mechanism for being able to track and manage those consent preferences at the level of the pathology service. A consent management system that could be integrated with the MyHR and preferably visible and linked to the test report would be the most transparent option.

While there remain relatively few genetic and genomic tests reimbursed by Medicare, the requirement to upload reports before reimbursement can be obtained by labs may bear less influence on some laboratories who rely mainly on other sources of funding. Where pathology services are reluctant to upload genetic and genomic tests results, and there are non-MBS item number reimbursement options, other avenues to pay for the tests (block funding, hospital, ABF) may be chosen to avoid having to upgrade systems and upload to MyHR.

3 How can we most effectively provide or communicate change and adoption resources for:

Consumers::

The Australian Government and Digital Health Agency need to put public awareness/education campaigns in place for this significant advance in the role of MyHR. The Australian public will need to be educated in what sharing imaging and pathology reports to MyHR by default means (i.e., it is not just them who can see their report, but potentially other HCPs involved in their care) and be aware of their rights to opt out of sharing, and how they can easily do this.

Organisations delivering diagnostic imaging and pathology services::

Through organisations such as NPAAC, NATA, RCPA and Pathology Technology Australia for pathology services.

Staff in organisations delivering diagnostic imaging and pathology services::

Staff will be guided by their organisational policies, which are informed by organisations governing their operations such as NATA for pathology services.

Treating healthcare providers who may request tests and/or use test results::

It will need to be easier, more informative, more accessible and more user friendly than their current systems for test requesters to use MyHR to access results. It is unclear whether the RACGP and other clinical professional organisations such as RACP have been consulted and whether they welcome these changes. It is likely clinicians will need to be supported to ensure patients are consulted to discuss their test results prior to their accessing them in the MyHR environment.

4 What current laws or organisation policies prevent diagnostic imaging and pathology providers from sharing reports to My Health Record?

List current laws or organisation policies that prevent diagnostic imaging and pathology providers from sharing reports to My Health Record :

Organisational policies of diagnostic laboratories performing genomic/genetic tests may, for example, prevent patients being able to see reports prior to a result return appointment with a genetic counsellor or other HCP. These organisational policies may also extend to the clinical genetics services, and so it will be necessary for the Australian Digital Health Agency to explore the organisational policies at play in relation to genetics/genomics and likely other disciplines of pathology to determine where barriers may arise.

5 What barriers, if any, do you foresee to your organisation sharing by default from December 2024?

List any barriers you foresee to your organisation sharing by default from December 2024:

If sharing is mandated, then organisations will comply, but the main barrier will be to organisations whose software systems still have inadequate interoperability with MyHR. The Australian Digital Health Agency has said that financial support will not be provided to laboratories to complete required upgrades. If the costs of these upgrades put laboratories under financial strain those costs will ultimately be shifted to the patients who access the services. This will happen in an environment where laboratories are already finding that reimbursement rates almost insufficient to cover the costs of new genomic tests on the MBS.

Another barrier may be that laboratories, or the clinical genetics organisations they service, have privacy or other concerns for patient safety.

It is currently unclear how compliance will be monitored and if there will there be evaluation to monitor the success of the new policy. Evaluation data specific to the Australian context will be important as MyHR introduces further requirements of organisations with respect to sharing data. There will need to be clear examples of the value to clinicians and patients and there are questions arising about how useful an incomplete MyHR will be, or how useful one will be where visibility controls have been applied.

6 What would prevent or overcome the barriers identified in the previous question?

List anything that would prevent or overcome the barriers identified in the previous question:

With respect to the views of consumers, more evidence for the proposed functions of MyHR is needed. The quotes and research cited in the consultation papers Part A and B are limited and at times not relevant to the Australian population. For example, citizens of the Nordics are used to having different aspects of their health and other information connected and have comfort with this. This is not so for the Australian population – an example being the abandoned proposal for the 'Australia Card' national identity card to be introduced in the 1980's. The Australian population is also much more heterogenous; a representation of many cultures including First Nations, migrant, and refugee populations who have limited trust in governments due to historical wrong doings. It would be naïve to assume that any research carried out in this area is broadly applicable across cultural groups.

Better access – sharing pathology and diagnostic imaging reports to My Health Record by default

1 What improvements to existing software for diagnostic imaging and pathology services would help them upload diagnostic imaging and pathology reports by default? This includes the ability to keep a record of reasons why they have not uploaded a report.

List improvements to existing software for diagnostic imaging and pathology services that would help them upload diagnostic imaging and pathology reports by default:

2 What barriers are there to better interoperability of My Health Record with existing software for diagnostic imaging and pathology customers?

List the barriers that exist to better interoperability of My Health Record with existing software for diagnostic imaging and pathology customers:

3 What opportunities are there for more automated management of reports? This includes sharing to My Health Record and documenting exceptions to reporting requirements.

List the opportunities that exist for more automated management of reports:

4 What barriers are there to more automated management of reports? This includes sharing to My Health Record and documenting exceptions to reporting requirements.

List the barriers that exist to more automated management of reports?:

Better access – sharing pathology and diagnostic imaging reports to My Health Record by default

1 What do you think will be the impact of diagnostic imaging and pathology providers having to share reports to My Health Record by default? This includes the impact on:

Consumers and/or carers::

We believe the intended outcome of this initiative - to empower consumers to have more control over their healthcare – should be viewed as a long-term goal. In the short term, there is likely to be a significant period of adjustment, knowledge building and consumers are likely to have elevated privacy concerns. There will also be necessary upskilling in the use of digital technologies for many. Australian Genomics delivered dynamic consent, an ICT, for projects including the Mackenzie's Mission Australian Reproductive Carrier Screening study and the Cardiovascular Genetic Disorders Flagship. For the latter, an evaluation found that using a dynamic consent platform was acceptable to users, and they were able to navigate the platform and make consent choices related to the secondary use of their health and genomic data.

However, it is unclear what consumer engagement has been done ahead of these changes and whether the proposed changes are seen as advantageous by most consumers. There is a risk that these changes may only be beneficial for the most informed consumers and could risk clinical safety for others. That is, what are the risks associated with people accessing results that may be interpreted wrongly, misunderstood, or create anxiety if accessed reports indicate a worsening of a condition or worse diagnoses than expected? What are the risks associated with a minor gaining access to their MyHR at 14 years of age and their parent/guardian losing access? Will Government undertake regular engagement or audits with consumers and clinicians to identify what the impact of having results in the MyHR environment earlier than when a clinician can contact a patient to discuss them?

Healthcare providers::

It would be good for the Australian Digital Health Agency to share with stakeholders the expected efficiencies gained for HCPs. Presumably the main goals are to reduce emergency presentations and to strengthen and relieve pressure on primary care. These changes may need to be accompanied by an increase in capacity and expansion of roles like practice nurses.

The broader healthcare system::

There is need to consider how this system can be geared toward the most disadvantaged when it comes to efficiencies of health care. How can better access to test results improve outcomes for Aboriginal and Torres Strait Islander Peoples, those who live regional/rural/remote areas, have low literacy (including health and IT literacy), and low socioeconomic groups. There needs to be a strategy to avoid the "worried well" totally overwhelming the health system while others with more immediate needs miss out.

2 What does the government need to consider when developing requirements to share diagnostic imaging and pathology results to My Health Record? Particularly consider:

List government considerations when developing requirements to share diagnostic imaging and pathology results to My Health Record:

Clinical safety – As discussed in response to a previous question, risks associated with people accessing results are that may be interpreted wrongly, misunderstood, or create anxiety if accessed reports indicate a worsening of a condition or worse diagnoses than expected. This may be amplified if there is then a waiting time to speak to an HCP about the result. Such responses are also highly dependent on the individual and it may not be easy to identify at risk patients.

Consumers' control of their health information – It is noted that under the My Health Record Act consent is not required to upload results to MyHR. However, easy opt outs, and ways to restrict visibility of certain reports as a consumer choice should be introduced. Does the Australian Digital Health Agency have data about the number of consumers who have been able to actively manage the visibility of the reports in their record, and the number of people who have opted out of sharing to MyHR in the first place? How many people access their MyHR and how many Aboriginal and Torres Strait Islander Peoples access their MyHR (in the past many Aboriginal and Torres Strait Islander Peoples did not want or use an MyHR and barriers in rural and remote areas included computer literacy, internet access, health literacy and lack of linkages with other specific healthcare programs)? The mention in the consultation document of working with and strengthening Aboriginal Community Controlled Health Organisations (ACCHOs) is positive but it is not clear what will be done and how it will be done.

Privacy – The Australian Digital Health Agency will already be highly aware that there should be ongoing engagement to inform the public about how MyHR is kept secure in the current environment where several high-profile data breaches have occurred. However, the public should also be informed about how their data is being used for health system research and planning, and development of new policy.
One potential feature that may increase trust with consumers is if there is an accessible log showing who has accessed their reports and when (if this feature doesn't already exist).

Quality of information available in records – The quality of information in the records would benefit from standardised reporting frameworks. Quality will also increase with completeness of records - improving access to health information to improve health care (particularly in emergency situations) is a worthwhile pursuit, but if the records are incomplete (i.e., people opt to not include or make visible some or all test results) then these gaps are significant when reviewing a patient's MyHR in these emergency situations. The case studies presented in the consultation materials did not speak to the value of the MyHR in an emergency – for example, HbA1c is a blood glucose measurement over time.

3 Please share any advice or comments not covered by previous questions.

List any additional advice or comment not already covered:

The proposed policy changes represent an important opportunity to make other improvements to pathology reports, including enforcing the use of standardised and atomic reports and linking the test report to information about the consent provided by the patient. Consent information is complex and critical for asserting choices of patients undergoing genomic testing. The NPAAC guidelines state that for Level 3 genomic tests (such as whole exome or genome sequencing), the laboratory must document patient decisions regarding:
"a. return of unsolicited findings, including unexpected familial relationships
b. data sharing of potentially re-identifiable data for clinical care
c. data sharing for ethically approved research
d. opt out if results are not to be included in the My Health Record"
Therefore, one way to ensure that all parts of the healthcare system act in accordance with the consent provided by the patient is to have the consent information linked to the report in MyHR.

Faster access – removing delays to accessing pathology and diagnostic imaging reports in My Health Record

1 What do you think would be the impact of consumers having immediate access to diagnostic imaging and pathology reports in their My Health Record? This includes the impact on:

Consumers and/or carers::

Having immediate access to pathology results may lead a patient to turn to Google for answers on how to interpret those results and/or they may experience psychological impacts while they wait for consultation with an HCP to discuss results. For these reasons it is crucial that there are clear guidelines in relation to when genetic/genomic test results can and cannot be shared directly to MyHR. It is likely that no tests aside from pharmacogenomics results or low chance reproductive carrier screening results should be shared prior to HCP consultation.

Healthcare providers::

Immediate access by patients to reports will put more pressure on HCPs. They will likely have to manage misinformation as patients turn to Google. Currently, clinical genetics services are under pressure, and the average time between a result being made available by the laboratory and a result return appointment may be months. Data from Australian Genomics Cardiovascular Genetic Disorders Flagship (2019 – 2022), where genomic testing was offered through standard clinical pathways, indicated an average time between issue of report and return of results in a clinical appointment of 44 days.

Noting that this timeframe occurred in clinical research where staff were specifically employed for this purpose.

The broader healthcare system::

One could anticipate that there will be more pressure on parts of healthcare system including primary care, because patients will be seeking follow-up appointments to discuss results that they may have already accessed via MyHR. However, if the policy changes achieve their aim, there will be efficiencies in other areas of the healthcare system such as emergency departments. It is also argued that upload by default will reduce duplicate testing and unnecessary treatments – though supporting evidence (e.g., from MBS testing data and PBS) about the current scale of this problem would be welcomed.

2 What resources should consumers have access to when they view a result in My Health Record? This question is about how to support consumers in a model of care where they have near real time access to their pathology and diagnostic imaging results.

List the resources that consumers should have access to when they view a result in My Health Record?:

All pathology reporting templates should be reviewed and assessed for ease of interpretation of results by consumers. Best practice would be for this process to engage consumers in a co-design process. Pathology reports should also be subject to standardisation and quality requirements. As part of a previous Australian Genomics project that sought to mainstream genomic test reports, considerations for a standard template were developed. Further to that, a one-page patient friendly report was developed by the Australian Genomics Acute Care Genomics program (rapid whole genome sequencing for critically ill infants), which could be taken up more broadly given the policy make reports accessible through MyHR. This patient friendly report was found to be highly valued by participants in the program.

3 What safety features could ensure follow-up clinical care happens promptly?

List the safety features that could ensure follow-up clinical care happens promptly:

The Australian Digital Health Agency should consider safety features such as including alerts to the requesting HCP when their patient has viewed their imaging or pathology report. Potentially distressing reports could be marked so that the patient is aware before they access them. Contact details for where to find support should also be provided.

4 Please share any advice or comments not covered by previous questions.

Share any advice or comments not covered by previous questions:

Overall Australian Genomics is supportive of a policy to increase utilisation of MyHR so that Australians can experience the benefits of more integrated care. However, this should be done with extensive consultation with consumers and HCPs. There are circumstances where careful consideration to the sharing of test reports (including the timing of sharing) needs to be considered, such as for genetic/genomic test results. We outline that sharing genetic/genomic test reports without prior discussion with the requesting HCP may only be relevant in a few situations, for example pharmacogenomic results or low chance reproductive carrier screening results. Whether it should be a case-by-case decision to upload genetic/genomic test reports should be explored further, as these tests can be done in complex clinical and family circumstances where the genetic HCP knowledge of the patient would be useful to incorporate in decision making about availability and timing of reports.

We believe the framing of this proposal, evidence cited, and case studies provided in the consultation papers potentially over-estimates the current health literacy of the broader Australian public. The two case studies outline the actions of highly health literate individuals who are actively involved and already experienced in managing their chronic conditions.

The proposed policy changes represent a time to consider related opportunities, for example to include upload of the consent form for genomic testing and introduce dynamic consent records of patient preference for sharing data to research. There is also an opportunity to support national digital standard for genomic test reports - including atomic reporting.

The proposed impact of these policy changes, empowering patients to take control of their own health data, may also shift the social concept of "ownership" of the patient's health data from being owned by the pathology/health service to the patient, which will have follow on implications.

We thank the Australian Digital Health Agency for the opportunity to comment on the proposed changes and will gratefully take part in any further planned consultation.

Publishing your responses

1 Response Publishing

Publish response, including both my name and organisation's name

Submission acknowledgement

1 Submission acknowledgement

Submission acknowledgement :
Yes